

REMARKS

Claims 1-60 are pending in this application and are currently under examination. Claims 1-3, 5-8, 24, 25 and 49 stand rejected. Claim 41 is now canceled by Applicants without forfeiting any right to pursue canceled subject matter in a subsequent divisional or continuation application. Claims 1, 3, 6 and 18 have been amended. Attached hereto is a marked-up version of the changes made to the claims by the current amendment. The attached page is captioned "Version with markings to show changes made."

Applicants thank the Examiner for the telephonic interview on January 21, 2003. During this telephonic interview, the prior art rejections were discussed and a number of amendments to the claims proposed that overcome the prior art rejections. Applicants thank Examiner Badio for her time.

Amendments to claims 1 and 6 are intended to remove non-preferred subject matter. Claim 1 has been further amended to add a substituted alkyl, "alkyl-alkoxy", as a substituent for R<sup>3</sup>. This amendment finds support with compound 91 in Figure 5, and in the definition of alkyl, page 5, lines 16-21:

As used herein, the term alkyl encompasses "substituted alkyls." Substituted alkyl refers to alkyl as just described including one or more functional groups such as lower alkyl, aryl, aralkyl, acyl, halogen (*i.e.*, alkylhalos, *e.g.*, CF<sub>3</sub>), hydroxy (*e.g.*, hydroxymethyl), amino, alkylamino, acylamino, acyloxy, **alkoxy** (*e.g.*, methoxymethyl), mercapto and the like. These groups may be attached to any carbon atom of the lower alkyl moiety. (emphasis added)

The first proviso of claim 1 has also been amended to remove prior art compounds disclosed in Acosta *et al.* from the scope of the present invention. As amended, this first proviso recites: if R<sup>1</sup> is -N(CH<sub>3</sub>)<sub>2</sub> or -NHCH<sub>3</sub>, R<sup>2</sup> is hydrogen, R<sup>3</sup> is acetyloxy and R<sup>4</sup> is methyl, then X is other than =O. Claim 3 has been amended to correct a minor typographical error, and claim 18 has also been amended to correct a missing claim dependency. These amendments are directed to formal matters and they introduce no new matter to the claims.

Applicants believe no new matter is present in this or any other portion of the present amendment.

Reconsideration of the application is respectfully requested in view of the above amendments to the claims and the following remarks. For the Examiner's convenience and reference, Applicants' remarks are presented in the order in which the corresponding issues were raised in the Office Action.

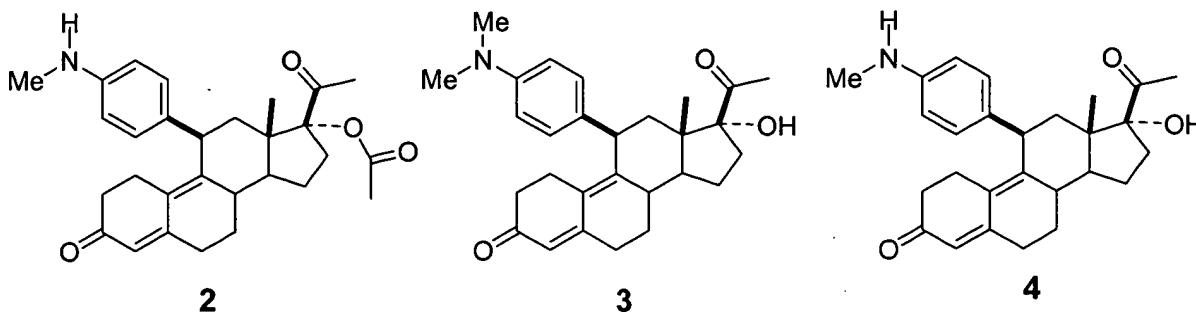
### **I. Provisional Obviousness-Type Double Patenting Rejection**

The Examiner has provisionally rejected claims 1-3, 5-8, 24, 25 and 49 under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over claims 1-26 of copending U.S. Patent Application No. 09/180,132. Upon notification that allowable subject matter is present in the instant application, Applicants will file the appropriate Terminal Disclaimer under 37 CFR § 1.321(c) to overcome the rejection.

### **II. Rejection under 35 U.S.C. § 102(b) in view of Acosta *et al.***

The Examiner has rejected claims 1-3, 6-8 and 49 of the instant application under 35 U.S.C. § 102(b) as allegedly being anticipated in view of Acosta *et al.* (*J. Chem. Soc., Chem. Commun.* 1994, 1985). To the extent the rejection is applicable to the amended set of claims, Applicants respectfully traverse the rejection.

The Examiner alleges that compounds 2-4 of Acosta *et al.* are encompassed by the claims of the instant application



Applicants respectfully disagree. Again, Applicants respectfully note that in claim 1 of the instant invention, R<sup>3</sup> (corresponding to the 17 $\alpha$  position) has been amended to remove hydroxy and alkyl substituents, and now claims "alkyl-alkoxy, alkoxy and acyloxy." As R<sup>3</sup> does not encompass hydroxy, the claims of the instant invention do not encompass compounds 3 and 4 of Acosta *et al.* In addition, Applicants respectfully point out to the Examiner the proviso in claim 1, lines 17-18, "if R<sup>1</sup> is -N(CH<sub>3</sub>)<sub>2</sub> or -NHCH<sub>3</sub>, R<sup>2</sup> is hydrogen, R<sup>3</sup> is acetyloxy and R<sup>4</sup> is methyl, then X is other than =O." This proviso specifically excludes compound 2 of Acosta *et al.* from the claims of the instant application, since X cannot be =O when R<sup>1</sup> is -N(CH<sub>3</sub>)<sub>2</sub> or -NHCH<sub>3</sub>, R<sup>2</sup> is hydrogen, R<sup>3</sup> is acetyloxy and R<sup>4</sup> is methyl.

As the Examiner is aware, the cited reference must teach every element of the claim, MPEP § 2131:

A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.

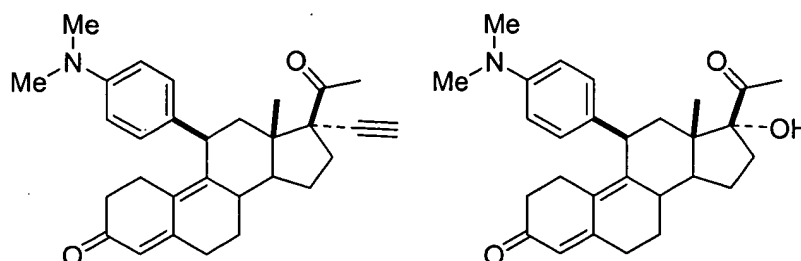
Verdegaal Bros. v. Union Oil Co. of California, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987).

As the amended claims of the instant application do not teach the specific elements needed to construct the compounds of Acosta *et al.*, Applicants respectfully submit that Acosta *et al.* does not anticipate the claims of the instant application. Accordingly, Applicants respectfully request the rejection be withdrawn.

### **III. Rejection under 35 U.S.C. § 102(b) in view of Cook *et al.***

The Examiner has rejected claims 1-3, 6-8 and 49 under 35 U.S.C. § 102(b) as allegedly being anticipated by Cook *et al.* (U.S. Patent No. 5,073,548). To the extent the rejection is applicable to the amended set of claims, Applicants respectfully traverse the rejection.

The Examiner alleges that the following compounds of Cook *et al.* are encompassed by the claims of the instant application



Applicants respectfully disagree. Again, Applicants note that in claim 1 of the instant invention, as discussed above,  $R^3$  (corresponding to the  $17\alpha$  position) has been amended to remove hydroxy and alkyl substituents, and now claims substituents “alkyl-alkoxy, alkoxy and acyloxy.” The specification of the present application defines alkyl as “a branched or unbranched, saturated or *unsaturated*, monovalent hydrocarbon radical having from 1-12 carbons” (page 5, lines 12-13, emphasis added). Thus, removing “alkyl” from  $R^3$  removes substituents such as ethenyl and ethynyl. As  $R^3$  of the present application no longer encompasses hydroxy or alkyl, the claims of the instant invention do not encompass the compounds of Cook *et al.*, and thus, Cook *et al.* does not anticipate the claims of the present application under MPEP § 2131. Accordingly, Applicants respectfully request that the rejection be withdrawn.

#### IV. Rejection under 35 U.S.C. § 103(a) in view of Peeters *et al.*

The Examiner has maintained the rejection of claims 1-3, 5-8, 24, 25 and 49 under 35 U.S.C. § 103(a) in view of Peeters *et al.* (U.S. Patent No. 5,741,787). To the extent the rejection is applicable to the amended set of claims, Applicants respectfully traverse the rejection.

The Examiner alleges that “the  $17\alpha$ -alkynes substituent taught by Peeters is encompassed by the claimed invention.” Applicants respectfully disagree. Applicants note that in claim 1 of the instant invention, as discussed above,  $R^3$  (corresponding to the  $17\alpha$  position) has been amended to replace “alkyl” with “alkyl-alkoxy.” The specification of the present application defines alkyl as “a branched or unbranched, saturated or *unsaturated*, monovalent hydrocarbon radical having from 1-12 carbons” (page 5, lines 12-13, emphasis added). Thus,

removing “alkyl” from R<sup>3</sup> removes alkynes, such as ethenyl and ethynyl, from the scope of the amended claims.

As amended, claim 1 of the instant application recites “alkyl-alkoxy, alkoxy and acyloxy” for R<sup>3</sup> (the 17 $\alpha$  position). In contrast, Peeters *et al.* teach *only* alkynes at the 17 $\alpha$  position. Accordingly, Applicants state that there is simply no motivation or suggestion provided in the cited reference to modify their teachings in the way the Examiner has contemplated. Obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988); *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992).

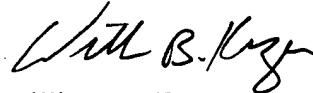
Applicants submit that one of skill in the art, starting from the alkynes of Peeters *et al.*, would not arrive at the alkyl-alkoxy, alkoxy and acyloxy of the present invention. Accordingly, Applicants submit that the present invention is not obvious in view of Peeters *et al.*, and respectfully request that the rejection be withdrawn.

CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 925-472-5000.

Respectfully submitted,



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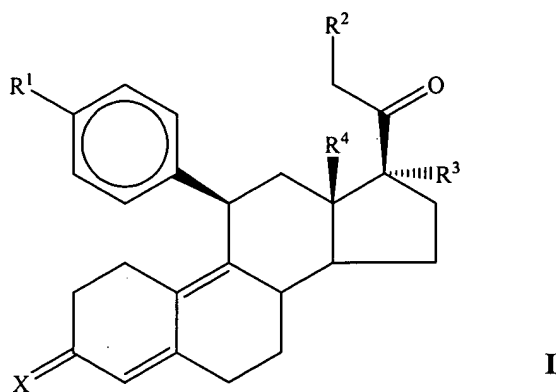
**VERSION WITH MARKINGS TO SHOW CHANGES MADE**

**In the claims:**

Claim 41 has been cancelled.

Claims 1, 3, 6 and 18 have been amended as follows:

1. (Twice Amended) A compound having the general formula:



wherein:

R<sup>1</sup> is a member selected from the group consisting of -OCH<sub>3</sub>, -SCH<sub>3</sub>, -N(CH<sub>3</sub>)<sub>2</sub>, -NHCH<sub>3</sub>, -NC<sub>4</sub>H<sub>8</sub>, -NC<sub>5</sub>H<sub>10</sub>, -NC<sub>4</sub>H<sub>8</sub>O, -CHO, -CH(OH)CH<sub>3</sub>, -C(O)CH<sub>3</sub>, -O(CH<sub>2</sub>)<sub>2</sub>N(CH<sub>3</sub>)<sub>2</sub>, -O(CH<sub>2</sub>)<sub>2</sub>NC<sub>4</sub>H<sub>8</sub>, and -O(CH<sub>2</sub>)<sub>2</sub>NC<sub>5</sub>H<sub>10</sub>;

R<sup>2</sup> is a member selected from the group consisting of hydrogen, halogen, alkyl, acyl, hydroxy, alkoxy, acyloxy, alkylcarbonate, cypionyloxy, S-alkyl, -SCN, S-acyl, and -OC(O)R<sup>6</sup>, wherein R<sup>6</sup> is a member selected from the group consisting of alkyl, alkoxy ester and alkoxy;

R<sup>3</sup> is a member selected from the group consisting of **[alkyl, hydroxy]alkyl-alkoxy**, alkoxy and acyloxy;

R<sup>4</sup> is a member selected from the group consisting of hydrogen and alkyl;

X is a member selected from the group consisting of =O and =N-OR<sup>5</sup>, wherein R<sup>5</sup> is a member selected from the group consisting of hydrogen and alkyl; and

wherein:

17                   if R<sup>1</sup> is -N(CH<sub>3</sub>)<sub>2</sub> or -NHCH<sub>3</sub>, R<sup>2</sup> is hydrogen, R<sup>3</sup> is acetyloxy and R<sup>4</sup> is methyl,  
18 then X is other than =O; and  
19                   if R<sup>1</sup> is -N(CH<sub>3</sub>)<sub>2</sub>, R<sup>2</sup> is hydroxy, R<sup>4</sup> is alkyl and X is =O, then R<sup>3</sup> is other than  
20 hydroxy.

1                   3.       (Amended) The compound in accordance with claim 1, wherein R<sup>2</sup> is a  
2 member selected from the group consisting of hydrogen, [alcyloxy]acyloxy, alkoxy, -SAc,  
3 -SCN, -OC(O)CH<sub>2</sub>N(CH<sub>3</sub>)<sub>2</sub>, and -OC(O)R<sup>6</sup>, wherein R<sup>6</sup> is a member selected from the group  
4 consisting of alkyl, alkoxy ester and alkoxy.

1                   6.       (Twice Amended) The compound in accordance with claim 1, wherein R<sup>3</sup>  
2 is a member selected from the group consisting of alkoxy[,]and acyloxy[ and hydroxy].

1                   18.     (Amended) The compound in accordance with claim 1, wherein:  
2                   R<sup>1</sup> is -N(CH<sub>3</sub>)<sub>2</sub>;  
3                   R<sup>2</sup> is hydrogen;  
4                   R<sup>3</sup> is methoxy;  
5                   R<sup>4</sup> is methyl; and  
6                   X is =O.